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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,582	03/29/2005	Silverio Casolaro	1303-154	9034

23117 7590 08/09/2006

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EXAMINER	
DIRAMIO, JACQUELINE A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/529,582	CASOLARO ET AL.	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/29/05; 5/31/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

The amendments to claims 4, 6 and 8 are acknowledged.

Currently, claims 1 – 9 are pending and under examination.

Claim Objections

Claim 5 is objected to because of the following informalities:

The recitation of claim 5 is unclear and perhaps should recite "wherein the porous support is in the form of a strip..."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the terms "the kit" and "the rack," which lack antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 2002/0001854) in view of L. Debrabandere et al. ("Development of a Fluoroimmunoassay for the Detection of Buprenorphine in Urine," Journal of Forensic Sciences, Vol. 40, No. 2 (1995) 250-253) and Hainfeld et al. (US 5,360,895).

Lee teaches an assay device (diagnostic device) for the determination of drugs of abuse, such as opiates/morphine, marijuana, cocaine, methamphetamine, etc., in a biological fluid, wherein said device comprises a porous support divided into a tracer zone (first zone) on which labeled anti-drug antibodies have been absorbed, a binder zone (second zone) on which the drug of abuse has been immobilized, and a third zone, i.e. sample integrity monitoring pad, on which immunoreactive substances that give a different antigen-antibody reaction, independently of the presence of the drug in the sample to be analyzed, are absorbed (see Figures 1 – 3; and paragraphs [0011], [0015], [0027]-[0032], [0040], [0044], [0052]-[0057], [0064], [0065], [0083], and Example 1).

However, Lee fails to teach the determination of buprenorphine specifically, or that the anti-drug antibodies are labeled with gold clusters.

Debrabandere et al. teach a method for the detection of buprenorphine in urine samples utilizing derivatives of the drug, antibodies to the drug, and a fluorescent label. Buprenorphine comprises a drug of abuse that is in the opiate family and displays opioid partial agonist properties. Because of the increasing rate of abuse of this opiate, buprenorphine, a sensitive, specific and rapid analysis technique is mandatory (see p250).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include buprenorphine as one of the opiates detected in the device of Lee because Debrabandere et al. teach that buprenorphine is in the opiate family of drugs and represents a drug of abuse and because of the increasing rate of abuse of this opiate, buprenorphine, a sensitive, specific and rapid analysis technique is mandatory.

However, Debrabandere et al. also fail to teach the labeling with gold clusters.

Hainfeld et al. teach the production of antibody-gold cluster conjugates that are useful as probes for microscopy and in immunoassays, wherein proteins or other materials that are absorbed to a solid phase are bound by the gold clusters, enabling the detection of the absorbed materials. The antibody-gold cluster conjugates are a significant improvement over the known compositions of materials conjugated with antibodies because of their small size and ability to load more than a few atoms onto the proteins, thus allowing for enough gold atoms to be contained within the conjugated

gold cluster in order for the cluster to be visible and detectable, which also improves signal-to-noise ratios (see column 3, lines 16-39; and column 4, lines 19-48).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Lee and the detection of buprenorphine of Debrabandere et al. the use of gold clusters for the antibody labeling as taught by Hainfeld et al. because Hainfeld et al. teach that antibody-gold cluster conjugates are a significant improvement over the known compositions of materials conjugated with antibodies because of their small size and ability to load more than a few atoms onto the proteins, thus allowing for enough gold atoms to be contained within the conjugated gold cluster in order for the cluster to be visible and detectable, which also improves signal-to-noise ratios.

With respect to Applicant's claims 2-3, Lee teaches that the immobilized drug of abuse in the binder zone is conjugated with BSA (bovine serum albumin) (see paragraph [0090]).

With respect to Applicant's claim 4-5, Lee teaches that the porous support is in the form of a strip and is constituted by cellulose, preferably nitrocellulose (see Figures 1-3; and paragraphs [0045], [0055], and [0090]).

With respect to Applicant's claims 6-7, Lee teaches a housing (rack) that consists of a base and cover (two removable lids) that contains a plurality of the test strip devices, wherein the housing allows for separation of the strips from one another in

compartments that are open at each end from which the strips can be removed (see Figures 3A-3C; and paragraphs [0063]-[0067]).

With respect to Applicant's claim 9, Lee includes the teaching of the method of determining a drug of abuse in a biological fluid, and therefore, the method of determining buprenorphine as recited in Applicant's claim 9 is unpatentable over Lee in view of L. Debrabandere et al. and Hainfeld et al. for the same reasons as discussed above for the device of claim 1.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 2002/0001854) in view of L. Debrabandere et al. ("Development of a Fluoroimmunoassay for the Detection of Buprenorphine in Urine," Journal of Forensic Sciences, Vol. 40, No. 2 (1995) 250-253) and Hainfeld et al. (US 5,360,895), as applied to claim 1 above, and further in view of Casterlin et al. (US 6,372,515).

Lee, Debrabandere et al. and Hainfeld et al. fail to teach a transparent box that contains the kit comprising a plurality of the devices of claim 1.

Casterlin et al. teach a transparent container for holding a biological test sample as well as a test card containing a plurality of test strips that each test for a particular drug of abuse. The combination of the container and test card, containing a plurality of test strips, in one test unit minimizes a number of separate steps previously required to test for drugs abuse by 1) eliminating the transfer of the biological sample to the analysis device and 2) allowing the simultaneous detection of multiple analytes by

including a plurality of test strips that each test for a particular drug of abuse (see Figures 1 and 2; Abstract; and column 2, lines 8-63).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Lee, Debrabandere et al. and Hainfeld et al. a transparent container as taught by Casterlin et al. because Casterlin et al. teach the benefit of combining a transparent container and test card, containing a plurality of test strips, in one test unit in order to minimize a number of separate steps previously required to test for drugs abuse by 1) eliminating the transfer of the biological sample to the analysis device and 2) allowing the simultaneous detection of multiple analytes by including a plurality of test strips that each test for a particular drug of abuse.

Conclusion

No claims are allowed.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Sun et al. (US 5,238,652).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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